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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09 910,706 | 07/20/2001 | Paul F. Worley | JHU1520-2 | 3044 |

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EXAMINER

ALLEN, MARIANNE P

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1631

DATE MAILED: 05/20/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/910,706

Applicant(s)

WORLEY ET AL.

Examiner

Marianne P. Allen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 04 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) 1-9, 12 and 24-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 10, 11 and 13-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) 1-43 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election of Group III, originally filed claims 10-12, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Newly submitted claims 24-43 and claim 12 as amended are directed to an invention that is independent or distinct from the invention originally claimed and the elected method of Group III for the following reasons:

IV. Claim 24 is directed to a first pharmaceutical composition.

V. Claims 25-26 are directed to a first method of treatment.

VI. Claims 12 and 27-40 are directed to a method of identifying a compound that modulates a cellular response.

VII. Claim 41 is directed to a second pharmaceutical composition.

VIII. Claims 42-43 are directed to a second method of treatment.

The compositions of Groups IV and VII can be shown to be distinct from the products of Groups I and II and each other because they do not share structural or functional features. The methods of Groups V-VI and VIII can be shown to be distinct from the elected method of Group III and each other because they have different starting materials, method steps, and/or goals. The products of Groups I-II, IV, and VII can be shown to be distinct from the methods of Groups III, V-VI, and VIII because the products are either not used by any of the methods or could be used in multiple methods.

Claims 1-9, 12, and 24-43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 11.

Claims 10-11 and 13-23 are under consideration by the examiner.

Applicant is advised that the marked-up copy of the claims does not correspond to the clean copy of the claims. At least the clean copy of claim 12 is dependent upon claim 27 whereas the mark-up copy of claim 12 is dependent upon claim 26. Applicant is reminded that the clean copy takes precedence.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

Claim/Specification Objections

Claims 13 and 23 are objected to because of the following informalities:

Claim 13 fails to reference the appropriate SEQ ID NOS. Appropriate correction is required to the claim and any portion of the specification referencing these sequences. (See for

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example page 3, line 19.) Note that other portions of the specification disclose sequences without referencing the appropriate SEQ ID NOS. (See for example page 10, line 13.)

Appropriate correction is required.

Claim 23 recites "125I." The "125" should be superscripted to indicate that this is a radioactive isotope.

Claim Rejections - 35 USC § 112

Claims 10-11 and 13-23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 10-11 have been amended and claims 13-23 have been newly added. Applicant has pointed to the originally filed claims, Examples 6 and 7, and page 18. These pages do not support the claims as amended.

Claim 10 has been amended to remove limitations to "isolated" components. There is no basis for this more general concept. Note that page 3 and 18 refer to all isolated or purified components.

Claim 11 has been amended to refer to any metabotropic glutamate receptor (mGluR) rather than ones containing particular sequences (see for example claim 13). There is no basis for this more general concept. Note that page 4, lines 3-4, contemplates only mGluR comprising an SSSL or SSTL sequence.

New claim 16 recites "protein is in solid phase." There is no basis for this concept in the specification. Note that the specification on page 18 discloses that the protein is "coated onto a solid phase." These are not synonymous concepts.

New claim 18 recites "glutathione-S-transferase (GST)-pulldown." There is no basis for this concept in the specification. Examples 6 and 7 do not disclose this terminology.

New claims 18-19 are directed to detection limitations. However, these are not disclosed in Examples 6 and 7 with respect to methods of selecting a protein that interferes with binding of a synaptic activation protein. Examples 6 and 7 do not disclose adding a test compound and selecting a compound in view of changed binding when compared to a control. Furthermore, Examples 6 and 7 are with respect to a particular Homer protein and mGluR binding protein and not the general concept set forth in claim 10.

New claims 16 and 20-23 are directed to assay limitations. However, these are disclosed on page 18 with respect to mGluR5 or mGluR1 α and PI-linked mGluR activity. They are not generally disclosed with respect to any binding protein to which the synaptic activation protein binds as in claim 10.

Should this new matter rejection be overcome, at least the following enablement rejection would apply to claims 10-11 and 13-23.

The preamble of claim 10 recites "interferes with binding of a synaptic activation protein to a cellular binding protein in the mammalian central nervous system." The body of the claim includes no steps that would establish that the test compound if selected would act in this manner in the mammalian central nervous system (*in vivo*). That is, the synaptic activation protein of the

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method does not have to be naturally occurring and the binding protein to which the synaptic activation protein binds is not required to the cellular binding protein of the claim preamble nor a naturally occurring protein (see for example claims 21-23). As such, the claim as written would not necessarily achieve the goal stated in the preamble.

Claims 14 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 appears to be directed to the same method as claim 13. It is noted that mGluR5 contains SSSL and mGluR1 α contains SSTL. See at least Figures 9A and 9E. Clarification is requested.

Claim 15 is confusing in reciting "a Homer protein." Claim 10 limits the synaptic activation protein to one having at least 70% sequence identity to SEQ ID NO: 2. The specification appears to define a Homer protein more broadly. As such, it is unclear if the claim is improperly dependent because it broadens the independent claim or whether applicant intended the recitation of a Homer protein to refer specifically to SEQ ID NO: 2 itself.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Genbank Accession No. AA212542 (2/19/97) 19-Feb-1997 discloses a nucleic acid sequence with some identity to SEQ ID NO: 1. This reference was cited in the parent application.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 703-308-0666. The examiner can normally be reached on Monday-Friday, 8:30 am - 2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 703-308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Marianne P. Allen
Marianne P. Allen
Primary Examiner
Art Unit 1631

mpa
May 15, 2003